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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,697	07/27/2006	Pentti Korhonen	43289-223931	2415

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EXAMINER	
GEDEON, BRIAN T	
ART UNIT	PAPER NUMBER
3766	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,697	KORHONEN, PENTTI	
	Examiner	Art Unit	
	Brian T. Gedeon	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 24 March 2008 has been entered.

Response to Arguments

2. Applicant's arguments, see Remarks, filed 24 January 2008, with respect to the rejection of claims 34-66 under MacAdam et al. have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Goldreyer. Rejections under Goldreyer are presented below.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 34-66 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The recitation of the claimed invention is to perform cardiac

analysis based on a dynamic change in a p-wave. As claimed, the cardiac analysis does not produce a useful result. The analysis is considered to result in an abstract algorithm and not a useful, tangible product. Therefore it is considered that claims 34-66 lack utility. The claimed invention as a whole must be useful and accomplish a practical application. That is, it must produce a "useful, concrete and tangible result." *State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 149 F.3d 1368, 1373-74, 47 USPQ2d 1596, 1601-02 (Fed. Cir. 1998). The purpose of this requirement is to limit patent protection to inventions that possess a certain level of "real world" value, as opposed to subject matter that represents nothing more than an idea or concept, or is simply a starting point for future investigation or research (Brenner v. Manson, 383 U.S. 519, 528-36, 148 USPQ 689, 693-96 (1966); In re Fisher, 421 F.3d 1365, 76 USPQ2d 1225 (Fed. Cir. 2005); In re Ziegler, 992 F.2d 1197, 1200-03, 26 USPQ2d 1600, 1603-06 (Fed. Cir. 1993)). *See MPEP 2106.II.A*

5. Claims 34-51 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The method recited in claim 1 is considered to be an abstract algorithm, which in the end produces an abstract value. Based on recent Supreme Court precedent and recent Federal Circuit decisions, the Office's guidelines for a statutory method or process must (1) be tied to another statutory class (such as particular apparatus) or (2) transform underlying subject matter (such as an article or material) to a different state or thing. To qualify as a statutory process, the claim should positively recite the other statutory classes to which it is ties. *Diamond v. Diehr*, 450

U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409, U.S. 63, 71 (1972); *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> or
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 34, 38, 39, 41-48, 50, 52, 56, 57, 59-61, 63 and 65 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldreyer (US Patent no. 4,365,639).

In regard to claims 34, 52, and 65, Goldreyer describes a method and device that is capable of obtaining an ECG of a patient, col 6 lines 24-40. Within the obtained ECG, a p-wave is detected. The p-wave is then compared to previous p-p intervals, i.e., the reference template, col 8 lines 44-49, in order to detected differences in the waves. If there is less that a 10% difference, the p-wave is considered normal, col 9 lines 34-51.

In regard to claims 38, 39, 56, and 57, the system and method of Goldreyer acquires values that indicate that a p-wave is present, col 9 lines 1-4.

In regard to claims 41, 42, 49, and 59-61, Goldreyer composes a reference p-wave template by average the ten prior p-wave intervals sensed, col 8 lines 46-49.

In regard to claims 43-48 and 61, Goldreyer detects a p-wave loop and determines the area of said loop, col 7 lines 41-54 and col 8 lines 1-6.

In regard to claims 50 and 63, the detected p-p intervals of Goldreyer are stored for later comparison to recently detected intervals, col 8 lines 46-49.

8. Claims 34, 52, and 65 are rejected under 35 U.S.C. 102(e) as being anticipated by Thompson (US Publication no. 2003/0069609).

In regard to claims 34, 52, and 65, Thompson discloses a method and system for acquiring and analyzing ECG signals for variations in subsequently generated p-waves of the signal, para [0010].

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 35-37, 40, 53-55, 58, and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldreyer (US Patent no. 4,365,639) in view of Toole (US PG-Pub. 2002/0082510).

In regard to claims 35, 37, 53, 55, and 66, Goldreyer substantially describe the invention as claimed except for the focusing the cardiac analysis on the PQ- segment. Toole describes a method for analysis of the electrocardiogram and teaches that any segment of the ECG can be analyzed including the P, PQ, QRS, or ST-T segments, p 5 claim 7. Therefore, in view of this teaching it would be obvious.

In regard to claims 36, 40, 54, and 58, Goldreyer substantially describe the invention as claimed except for representing the ECG signal as a vectorcardiogram. Toole teaches that another known method of ECG analysis, called vectorcardiogram, involves utilizing 3 leads, X, Y, and Z, to represent coordinate planes of the patients chest and to identify where the lead voltage are located. Therefore it would be obvious to use vectorcardiogram techniques since Toole teaches that the vectorcardiogram is useful in diagnosing abnormalities of the heart, para [0004].

11. Claims 49, 51, 62, and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldreyer (US Patent no. 4,365,639) in view of MacAdam et al. (WO 02/058550).

In regard to claims 49 and 62, Goldreyer substantially discloses the invention as claimed except for the use of a 12 lead ECG to gather the ECG signals. MacAdam et al. teach that is well known in the art to use a 12 lead ECG in an attempt to correlate changes in P wave morphology, p 5 lines 8-10. The Examiner contends that it would have been obvious to one of ordinary skill in the art at the time the invention was made

to combine the processing elements in Goldreyer for comparing the p-p intervals with a 12 lead ECG in MacAdam et al. since it would involve combining elements of the prior art without changing the intended functions of the elements as disclosed.

In regard to claims 51 and 64, Goldreyer substantially discloses the invention as claimed except for the use of displaying the acquired data. MacAdam et al. teach that the signal sensed at a time instant by sensors placed on a patient's chest is plotted can be plotted on a display 16, p 16 lines 21-24 and p 18 lines 3-13. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify signal processing elements of Goldreyer to output the values to a display since MacAdam et al show that it is common in the art to graphically display acquired data.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ferek-Petric (US Publication no. 2005/0027321) and van Dam (US Publication no. 2004/0215238) both describe systems and methods for analyzing p-waves be comparing dynamic changes in their signal characteristics.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272-3447. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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